

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: :  
SHANLER et al. : Confirmation No.: 4999  
Application No.: 10/763,807 : Group Art Unit: 1627  
Filed: January 22, 2004 : Examiner: Carter, Kendra D.  
TITLE: METHOD AND THERAPEUTIC/COSMETIC TOPICAL COMPOSITIONS FOR  
THE TREATMENT OF ROSACEA AND SKIN ERYTHEMA USING A1-  
ADRENOCEPTOR AGONISTS

**Mail Stop Petition**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT**  
**PURSUANT TO 37 CFR §1.705(b)**

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.705(b), Applicant respectfully requests that the Patent Term Adjustment (PTA) calculated by the U.S. Patent and Trademark Office (PTO) in the above-referenced application be reconsidered. We have received a Notice of Allowance in this application and are filing this petition concurrently with payment of the issue fee. The Notice of Allowance indicates that this application is entitled to seven hundred and twenty-eight (728) days of Patent Term Adjustment. *See* Exhibit A. This is based on the PTO's calculations of specific delays of the Applicant and the PTO as reflected in the patent term adjustment history IFW page. *See* Exhibit B. The Notice of Allowance in the above-referenced application provides an estimated patent issue date of November 23, 2010. For the reasons set forth below, Applicant believes that it is entitled to a total patent term adjustment of one thousand five hundred and forty-eight (1548) days.

Applicant calculates the “A delay”<sup>1</sup> to be nine hundred thirty-six (936) days, the “B delay”<sup>2</sup> to be nine hundred sixty-nine (969) days, and the overlap<sup>3</sup> of “A delay” and “B delay” to be two hundred sixty-five (265) days. There is no “C delay.”<sup>4</sup> Applicant’s delay in this case is ninety two (92) days. This brings the total patent term adjustment,<sup>5</sup> to which Applicant is entitled, to one thousand five hundred forty-eight (1548) days ( $936 + 969 - 265 - 92 = 1548$ ).

In support of this request, Applicant submits the following information:

Filing Date:	01-22-2004
Third Anniversary of Pendency:	01-22-2007
Date of Filing of RCE	09-17-2009
Notice of Allowance date	05-14-2010

Based on the above information, Applicant calculates the Patent Term Adjustment as follows:

A delay calculation	Day after the 14 month date after the date on which application was filed (03-22-2005) and date when the <u>Restriction Requirement</u> was mailed (06-20-2007)	820 days
	Day after 4 month date after the date on which the Response to Office Action was filed (01-11-2008) and date when an <u>Office Action</u> was mailed (09-04-2008)	116 days

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<sup>1</sup> “A delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response.

<sup>2</sup> “B delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency.

<sup>3</sup> To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. See 35 U.S.C. § 154(b)(2)(A). As outlined in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), *aff’d* *Wyeth v. Kappos*, Fed. Cir. 2009-1120, decided January 7, 2010, the only way that these periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension of the patent term to one day. *Id.* The Federal Circuit reasoned that “the language of section 154(b) does not even permit B delay to start running until three years after the application is filed” and thus overlap cannot occur before the end of the three year pendency period. *Wyeth v. Kappos* at \*8.

<sup>4</sup> “C delays” are defined as delays by the PTO under 35 U.S.C. § 154(c), which extends patent term for delays caused by interferences, secrecy orders and appeals.

<sup>5</sup> The Patentees’ delay is subtracted from the PTO delay (calculated by the addition of A delay, B delay and C delay) to produce the total patent term adjustment.

B delay calculation	Day after Third Anniversary (01-22-2007) and <u>RCE</u> filing date (09-17-2009)	969 days
Overlap of A delay and B delay	Day after Third Anniversary (01-22-2007) and date when Restriction Requirement was filed (06-20-2007)	149 days
	Day after 4 month date after the date on which the Response to Office Action was filed (01-11-2008) and mailing of <u>Non-Final Office Action</u> (09-04-2008)	116 days
Applicant delay calculation	Day after 3 month date after the date on which a notice or action was mailed (06-17-2009) and ending on the date the reply was filed (09-17-2009).	92 days

This application is not subject to a terminal disclaimer.

Applicant is therefore entitled to a patent term adjustment of one thousand five hundred and forty-eight (1548) days. Applicant's calculation of the patent term adjustment is based on the projection that this patent will issue on the Tuesday before the date that is 28 weeks after the mailing date of the Notice of Allowance which is November 23, 2010 and Applicant reserves the right to petition for any further patent term adjustment after the patent issues.

In consideration of the information described above, Applicant believes that the Patent PTO's PTA calculation of seven hundred twenty-eight (728) days is incorrect. As such, Applicant respectfully requests reconsideration of the PTA in the following manner:

1. total PTO delay should be calculated as 1640 days (i.e., the sum of 936 days of "A delay," 969 days of "B delay," and 0 days of "C delay" minus the 265 days of overlap);
2. total Applicant Delay should be calculated as 92 days; and
3. total PTA should be calculated as 1548 days.

**AUTHORIZATION**

The Commissioner is hereby authorized to charge any fees which may be required for this paper, or credit any overpayment, to Deposit Account No. 50-0436.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "N. Nicole Endejann", written over a horizontal line.

N. Nicole Endejann

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Date: May 27, 2010

# **EXHIBIT A**



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
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Alexandria, Virginia 22313-1450  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,807	01/22/2004	Stuart D. Shanler	136519.00101	4999

21269 7590 05/14/2010

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PITTSBURGH, PA 15219

EXAMINER

CARTER, KENDRA D

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 05/14/2010

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 728 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 728 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# **EXHIBIT B**



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10/763,807

**METHOD AND THERAPEUTIC/COSMETIC TOPICAL COMPOSITIONS FOR THE TREATMENT OF ROSACEA AND SKIN ERYTHEMA USING A1-ADRENOCEPTOR AGONISTS**


Select New Case	Application Data	Transaction History	Image File Wrapper	Patent Term Adjustments	Published Documents	Address & Attorney/Agent	Assignments	Display References	Publication Review
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**Patent Term Adjustment**

Filing or 371(c) Date:	01-22-2004	USPTO Delay (PTO) Delay (days):	-
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	-	Applicant Delay (APPL) Delay (days):	-
Post-Issue Petitions (days):	-	Total Patent Term Adjustment (days):	728
USPTO Adjustment (days):	-	<a href="#">Explanation Of Calculations</a>	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
05-14-2010	Mail Notice of Allowance		
05-11-2010	Document Verification		
05-11-2010	Notice of Allowance Data Verification Completed		
05-11-2010	Case Docketed to Examiner in GAU		
05-10-2010	Examiner's Amendment Communication		
02-28-2010	Date Forwarded to Examiner		
01-20-2010	Response after Non-Final Action		
01-15-2010	Mail Examiner Interview Summary (PTOL - 413)		
01-07-2010	Examiner Interview Summary Record (PTOL - 413)		
12-21-2009	Mail Non-Final Rejection		
12-18-2009	Non-Final Rejection		
09-17-2009	Information Disclosure Statement considered		
10-06-2009	Date Forwarded to Examiner		
09-17-2009	Reference capture on IDS		
09-17-2009	Information Disclosure Statement (IDS) Filed		
10-06-2009	Date Forwarded to Examiner		
09-17-2009	Request for Continued Examination (RCE)		92
10-06-2009	Disposal for a RCE / CPA / R129		⬆
09-17-2009	Request for Extension of Time - Granted		⬆
10-06-2009	Case Docketed to Examiner in GAU		⬆
09-17-2009	Information Disclosure Statement (IDS) Filed		⬆
09-17-2009	Workflow - Request for RCE - Begin		⬆
09-16-2009	Mail Examiner Interview Summary (PTOL - 413)		⬆
09-02-2009	Examiner Interview Summary Record (PTOL - 413)		⬆
03-17-2009	Mail Final Rejection (PTOL - 326)		⬆
03-16-2009	Final Rejection		
01-10-2009	Date Forwarded to Examiner		
12-04-2008	Response after Non-Final Action		



10-14-2008	Mail Examiner Interview Summary (PTOL - 413)	
10-07-2008	Examiner Interview Summary Record (PTOL - 413)	
09-04-2008	Mail Notice of Withdrawn Action	
09-04-2008	Mail Non-Final Rejection	
09-02-2008	Non-Final Rejection	
09-02-2008	Date Forwarded to Examiner	
09-02-2008	Letter Withdrawing / Vacating Office Action	
06-13-2008	Mail Examiner Interview Summary (PTOL - 413)	
06-10-2008	Examiner Interview Summary Record (PTOL - 413)	
06-10-2008	Case Docketed to Examiner in GAU	
06-10-2008	Case Docketed to Examiner in GAU	
06-10-2008	Case Docketed to Examiner in GAU	
06-02-2008	Mail Examiner Interview Summary (PTOL - 413)	
05-28-2008	Examiner Interview Summary Record (PTOL - 413)	
05-28-2008	Case Docketed to Examiner in GAU	
04-15-2008	Mail Non-Final Rejection	
04-14-2008	Non-Final Rejection	
01-11-2008	Information Disclosure Statement considered	
01-11-2008	Information Disclosure Statement considered	
01-11-2008	Information Disclosure Statement considered	
01-11-2008	Information Disclosure Statement considered	
01-11-2008	Reference capture on IDS	
01-11-2008	Information Disclosure Statement (IDS) Filed	
02-02-2008	Date Forwarded to Examiner	
01-11-2008	Response after Non-Final Action	
01-11-2008	Information Disclosure Statement (IDS) Filed	
01-11-2008	Information Disclosure Statement (IDS) Filed	
10-20-2007	Mail Post Card	
10-12-2007	Email Notification	
10-12-2007	Mail Non-Final Rejection	
09-28-2007	Non-Final Rejection	
07-20-2007	Information Disclosure Statement considered	
08-08-2007	Case Docketed to Examiner in GAU	
07-20-2007	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	
07-25-2007	Date Forwarded to Examiner	
07-20-2007	Response to Election / Restriction Filed	
07-20-2007	Reference capture on IDS	
07-20-2007	Information Disclosure Statement (IDS) Filed	
07-20-2007	Information Disclosure Statement (IDS) Filed	
07-09-2007	Correspondence Address Change	
07-10-2007	Change in Power of Attorney (May Include Associate POA)	
06-20-2007	Mail Restriction Requirement	820
06-04-2007	Requirement for Restriction / Election	⬆
06-28-2006	Case Docketed to Examiner in GAU	⬆
04-27-2005	Miscellaneous Incoming Letter	⬆
04-19-2005	Miscellaneous Incoming Letter	⬆
08-10-2004	IFW TSS Processing by Tech Center Complete	⬆

08-10-2004	Case Docketed to Examiner in GAU	⬆
06-24-2004	Application Return from OIPE	⬆
06-24-2004	Application Return TO OIPE	⬆
06-24-2004	Application Dispatched from OIPE	⬆
06-24-2004	Application Is Now Complete	⬆
06-14-2004	Payment of additional filing fee/Preexam	⬆
06-14-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	⬆
04-28-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	⬆
03-09-2004	Cleared by OIPE CSR	⬆
01-31-2004	IFW Scan & PACR Auto Security Review	⬆
01-22-2004	Initial Exam Team nn	⬆

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